UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: DAVOL, INC./C.R. BARD, INC., POLYPROPYLENE HERNIA MESH PRODUCTS LIABILITY LITIGATION

Case No. 2:18-md-2846

JUDGE EDMUND A. SARGUS, JR.
Magistrate Judge Kimberly A. Jolson

This document relates to:
***Milanesi v. C.R. Bard*,**
Case No. 2:18-cv-01320

MOTIONS *IN LIMINE* OPINION AND ORDER NO. 38

Defendants' Motions *in Limine* ("MIL") Nos. 1, 4, 5

Currently before the Court are three motions:

(1) Defendants' MIL No. 1 to Exclude Evidence and Argument Concerning Composix Kugel Rings Breaks and Recall (ECF No. 172) and Plaintiffs' Memorandum in Opposition (ECF No. 264);

(2) Defendants' MIL No. 4 to Exclude Evidence and Argument Concerning Alleged Complications and Defects that Did Not Occur in this Case (ECF No. 176) and Plaintiffs' Memorandum in Opposition (ECF No. 263);

(3) Defendants' MIL No. 5 to Exclude Evidence and Argument Concerning FDA Inspections and Third-Party Audits (ECF No. 190) and Plaintiffs' Memorandum in Opposition (ECF No. 267).

For the reasons that follow, the Court **DENIES** and **DENIES IN PART** these motions as set forth below.

I.[1]

The Milanesi's case will be tried as the second bellwether selected from thousands of cases in this multidistrict litigation ("MDL") titled *In Re: Davol, Inc./C.R. Bard, Inc., Polypropylene Hernia Mesh Products Liability Litigation*, 2:18-md-2846. The Judicial Panel on Multidistrict Litigation described the cases in this MDL as "shar[ing] common factual questions arising out of allegations that defects in defendants' polypropylene hernia mesh products can lead to complications when implanted in patients, including adhesions, damage to organs, inflammatory and allergic responses, foreign body rejection, migration of the mesh, and infections." (Case No. 2:18-md-02846, ECF No. 1 at PageID #1–2.)

The relevant facts for the issue before the Court are as follows: The Ventralex hernia patch is a prescription medical device used for umbilical and small ventral hernia repairs. One side of the device contains polypropylene mesh, while the other contains a layer of polytetraflouroethylene ("ePTFE") layer. The ePTFE side is meant to face and protect the bowel as the device's polypropylene mesh incorporates into the tissue on the opposite side. Inside the device is a "ring" or "memory coil" that is meant to "spring open" so the patch lies flat against the abdominal wall once it is implanted. If that ring were to unintentionally fold inward (*i.e.*, "buckle"), it would risk exposing the bowel to bare polypropylene. This buckling has been known to cause various physical injuries, such as fistulae and adhesions.

The Ventralex comes in three sizes: small, medium, and large. The small and medium patches were released in July 2002, four years before the large patch. To market the small and medium patch, Bard needed to satisfy the Food and Drug Administration's ("FDA") section 510(k) premarket clearance process. This required Bard to demonstrate that the Ventralex's

[1] All docket citations are to the *Milanesi* case, 2:18-cv-1320, unless otherwise noted.

design was "substantially equivalent" to a device that the FDA had already fully approved (*i.e.*, a "predicate" device). In this case, the predicate device was Bard's Composix Kugel—which, like the Ventralex, contained a memory coil and ePTFE layer.

Between 2005 and 2006, Bard voluntarily recalled certain product codes of the Composix Kugel due to concerns that its memory coil could break. Around this time, Bard was subject to various FDA inspections and third-party audits.

In 2006, Defendants released the large version of the Ventralex patch. Because the patch was based on the small and medium versions, which, in turn, were based on the Composix Kugel, it was considered part of Bard's family of Kugel products. The Ventralex Large Hernia Patch was brought to market through a "no-510(k)" process.

On July 11, 2007, Mr. Milanesi underwent surgery to repair what appeared to be a recurrent hernia but was revealed to be a bowel erosion with a fistula and adhesions, which required a bowel resection. Dr. Karanbir Gill, Mr. Milanesi's surgeon, used a large Ventralex hernia patch in the reparation surgery. On May 25, 2017, Mr. Milanesi was diagnosed with a recurrent entrapped or obstructed ventral incisional hernia. He received emergency surgery the next day.

On June 1, 2017, Mr. Milanesi returned for another emergency surgery to remove a high-grade post-operative bowel obstruction caused by adhesions in the right lower quadrant. Subsequently, Mr. Milanesi developed a recurrent abdominal wall hernia near his previous surgery sites.

Plaintiffs allege that Mr. Milanesi's injuries resulted from the implantation of the large Ventralex patch. Specifically, they allege that Mr. Milenesi's Ventralex patch "buckled," causing its polypropylene side to adhere to his bowels, leading, in turn, to a high-bowel blockage

and, subsequently, multiple hospitalizations. Plaintiffs make three principal allegations to support their claim: (1) that "polypropylene resin oxidatively degrades *in vivo*," (2) that the ePTFE layer of the large Ventralex device contracts more than the polypropylene side, which in combination with the too-weak memory coil ring, causes the device to "buckle" or "potato chip," and (3) that the Ventralex's ePTFE layer was prone to infection because of its small pore size, which, they assert, is big enough for bacteria to grow in, but too small for white blood cells to enter to intercept the bacteria.

In addition to the Kugel product family, Bard markets the Ventralight ST—the hernia mesh device at issue in the first bellwether case of this MDL, *Johns v. CR Bard et al.*, No 2:18-cv-01509. Defendants anticipate that Plaintiffs will attempt to introduce evidence and argument concerning issues related to the Composix Kugel and the Ventralight ST. Defendants move to either limit and/or preclude this evidence at trial under Federal Rules of Evidence 402, 403, and 404.

II.

The parties move *in limine* for exclusion of evidence under Federal Rules of Evidence 402 and 403. "Neither the Federal Rules of Evidence nor the Federal Rules of Civil Procedure explicitly authorize a court to rule on an evidentiary motion *in limine*." *In re E.I. du Pont de Nemours & Co. C-8 Pers. Injury Litig*., 348 F. Supp. 3d 698, 721 (S.D. Ohio 2016). The practice of ruling on such motions "has developed pursuant to the district court's inherent authority to manage the course of trials." *Luce v. United States*, 469 U.S. 38, 41 n.4 (1984). "The purpose of a motion *in limine* is to allow a court to rule on issues pertaining to evidence prior to trial to avoid delay and ensure an evenhanded and expedient trial." *In re E.I. du Pont*, 348 F. Supp. 3d at 721 (citing *Ind. Ins. Co. v. Gen. Elec. Co.*, 326 F. Supp. 2d 844, 846 (N.D. Ohio 2004)).

However, courts are generally reluctant to grant broad exclusions of evidence before trial because "a court is almost always better situated during the actual trial to assess the value and utility of evidence." *Koch v. Koch Indus., Inc.*, 2 F. Supp. 2d 1385, 1388 (D. Kan. 1998); *accord Sperberg v. Goodyear Tire & Rubber Co.*, 519 F.2d 708, 712 (6th Cir. 1975).

Unless a party proves that the evidence is clearly inadmissible on all potential grounds—a demanding requirement—"evidentiary rulings should be deferred until trial so that questions of foundation, relevancy and potential prejudice may be resolved in proper context." *Ind. Ins. Co*., 326 F. Supp. 2d at 846; *see also Koch*, 2 F. Supp. 2d at 1388 ("[A] court is almost always better situated during the actual trial to assess the value and utility of evidence."). The denial, in whole or in part, of a motion *in limine* does not give a party license to admit all evidence contemplated by the motion; it simply means that the Court cannot adjudicate the motion outside of the trial context. *Ind. Ins Co.*, 326 F. Supp. 2d at 846.

Relevant evidence is "evidence having any tendency to make the existence of any fact that is of consequence to the determination of the action more probable or less probable than it would be without the evidence." Fed. R. Evid. 401. "Irrelevant evidence is" inadmissible. Fed. R. Evid. 402.

A court may exclude relevant evidence under Federal Rule of Evidence 403 "if its probative value is substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403.

Likewise, under Federal Rule of Evidence 404(b), a court must dismiss evidence of a party's past "wrong, crime, or act" that is introduced for the purpose of proving that, on some *other* occasion, the party acted accordingly. This bar on "character" evidence, however, does not

extend to evidence that is introduced for "another purpose, such as proving motive, opportunity, intent, preparation, plan, knowledge, identity, absence of mistake, or lack of accident." Fed R. Evid. 404(b).

Evidentiary rulings are made subject to the district court's sound discretion. *Frye v. CSX Trans., Inc.*, 933 F.3d 591, 598 (6th Cir. 2019); *see also Paschal v. Flagstar Bank*, 295 F.3d 565, 576 (6th Cir. 2002) ("In reviewing the trial court's decision for an abuse of discretion, the appellate court must view the evidence in the light most favorable to its proponent, giving the evidence its maximum reasonable probative force and its minimum reasonable prejudicial value.").

III.

The Court addresses together (A) Defendants' MIL Nos. 1 and 5, and separately (B) Defendants' MIL 4.

A. Defendants' MIL No. 1 and Defendants' MIL No. 5

In MIL 5, Defendants move *in limine* to exclude evidence of FDA inspections and audits performed by third-party auditors that Bard and Davol retained "to perform audits in order to help address the FDA communications, the audits primarily pertained to the Composix Kugel, not the Ventralex, and may occurred after Mr. Milanesi's implant.[2]" (Defs' MIL No. 5 at 2, ECF No. 190.) Similarly, in Defendants' MIL 1, Defendants move "for an order *in limine* to preclude Plaintiffs from presenting evidence or argument concerning Composix Kugel ring breaks and recall," because Plaintiffs do not contend that "the memory recoil ring in [Mr. Milanesi's] Ventralex broke . . . . [n]or was the Ventralex ever recalled." (Defs' MIL No. 1 at 1, 2, ECF No.172.) Defendants conclude from these two facts that the "Composix Kugel ring breaks and

[2] Evidence related to FDA inspections and third-party audits that may have occurred after Mr. Milanesi's implant will be addressed in a later MIL Order.

the recall have no relevance to this case, and would merely serve as fodder for jury confusion and wasted time, as well as impermissible character evidence." *Id*. This Court disagrees.

The Court first notes that this issue was briefed multiple times in *Johns*, and the Court ultimately held the evidence admissible to show Defendants' notice or knowledge, as long as the evidence was connected to Mr. Johns' injury, summarizing:

> For the reasons set forth on the record, the Court adheres to its prior rulings that evidence related to other devices, including the Composix Kugel, is admissible to show Defendants' notice or knowledge, . . . so long as that evidence is connected to Plaintiff's injuries in this case, adhesions from the Ventralight ST . . . .
>
> This includes the Court's specific determination that evidence of the Composix Kugel recall, FDA inspections, and third-party audits is relevant to whether Defendants were on notice of regulatory and statutory violations that also occurred during the manufacture of the Ventralight ST, including violations pertaining to Defendants' quality management systems and their design control process.

Johns v. C. R. Bard, Inc., et al., MIL Order No. 14 ("*Johns* MIL Order No. 14") at 1, Case No. 18-cv-1509, ECF No. 503. Thus, this Court permitted the evidence related to the Composix Kugel, its recall, FDA inspections, and third-party audits to show Defendants' notice or knowledge as long as that evidence was connected to Mr. Johns' injuries.

The Ventralex product at issue in the Milanesi case, unlike the Ventralight ST in *Johns*, utilized the Composix Kugel as the predicate device. This distinction makes the issues with the Composix Kugel relevant to Mr. Milanesi's case for more than the purpose of showing Defendants' notice or knowledge. Information from the Composix Kugel design process, including the post-market surveillance, would have informed Defendants' decisions that were being made in the Ventralex Large Hernia Mesh design process. These similarities underscore why evidence of the Composix Kugel problems, and ultimately its recall, are relevant. Part of Plaintiffs' theory of the case is that the Composix Kugel issues "explain[] why the Ventralex

buckled and, consequently, why Mr. Milanesi was injured. It explains, in short, the crux of Mr. Milanesi's case." (Mem. in Opp. at 2, ECF No. 264.)

Indeed, Stephen N. Eldridge, a member of Davol's research and development team, testified that at the time Mr. Milanesi was implanted with a Large Ventralex, the Ventralex and the Composix Kugel had the same components and very similar designs such that "the Small Composix Kugel that would have been sold could be replaced by the Large Ventralex." (Pls' Supp. Memo. in Opp. at 3, ECF No. 277) (citing Eldridge Dep. at 528:16–18; *see also id.* at 534:3–14, ECF No. 277-1).

This Court not only reviewed these Composix Kugel issues in *Johns*, but Defendants also drew attention to them in their motion to exclude Plaintiffs' expert, Dr. David Krpata, under Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). There, Defendants moved, *inter alia*, to prohibit Dr. Krpata from relying on documents pertaining to Composix Kugel ring breaks in forming his opinion regarding the strength of the ring in the Ventralex product implanted in Mr. Milanesi. *Id*. (citing Evidentiary Motions Order ("EMO") No. 17, ECF No. 166 at 24). In EMO No. 17, the Court specifically found that information relevant. The Court explained that

> " . . . the Composix Kugel Patch products have the same design and materials as the proposed large Ventralex Patch," including the memory recoil ring and excepting the Ventralex's positioning straps. (ECF No. 63-1 at PageID #1098.) Dr. Krpata offers an opinion that the ring in the Ventralex was too weak, and whether a ring bends or breaks are both questions about ring strength. This is sufficient for relevance.

EMO No. 17 at 24, ECF No. 166.

Thus, Defendants' focus on whether the ring broke or bent is far too narrow. The fact that the ring was not broken in the Ventralex product at issue here does not mean that the ring was not part of the cause of Mr. Milanesi's injury. Indeed, as Dr. Krpata opines, the ring in the

Ventralex was too weak, and whether a ring bends or breaks are both questions about ring strength. Plaintiffs' theory is that there is a direct causal connection between the Composix Kugel ring breaks and recall, the subsequent design of the Ventralex Large, and Mr. Milanesi's injury.

Further, evidence of the Composix Kugel ring breaks and recall is probative of Defendants' knowledge or notice of the risks posed by the Ventralex and other mesh products with similar designs or risk profiles. Defendants' alleged knowledge or notice of these risks is relevant to, among other things, Plaintiffs' negligence and punitive damages claims.

As to 403 balancing, Defendants contend that "the closer relationship of the Composix Kugel to the Ventralex makes the chance of jury confusion and prejudice greater, far outweighing whatever probative value there might be." This Court disagrees. The evidence related to the Composix Kugel is relevant to and probative of Plaintiffs' main theory of the case. This probative value is not substantially outweighed by a danger of jury confusion or any unfair prejudice.

Finally, Defendants assert that evidence of the Composix Kugel ring breaks and recall is prohibited character evidence under Federal Rule of Civil Procedure 404(b)(1). Plaintiffs, however, are not introducing this evidence to show that Defendants have a propensity to act with bad character. Rather, Plaintiffs inform that they anticipate introducing evidence of the Composix Kugel ring breaks and recall to tell the story of the Ventralex and how Mr. Milanesi was injured and to show Defendants' knowledge and notice of the buckling issue prior to Mr. Milanesi's implant. These uses are explicitly permitted under Rule 404(b)(2).

Accordingly, the Court **DENIES** Defendants' MIL No. 1 (ECF No. 172) and **DENIES** Defendants' MIL No. 5 (ECF No. 190).

B. Defendants' MIL No. 4

Defendants move for exclusion of evidence of complications and defects that did not occur in this case, contending that the evidence would be irrelevant, unduly prejudicial, confusing to the jury, and a waste of the Court's, the parties', and the jury's time. Specifically, "Bard moves for an order *in limine* to preclude Plaintiffs from presenting any evidence, testimony, reference to, or argument concerning: (a) alleged defects in and risks of the Ventralex Hernia Patch that did not cause Mr. Milanesi's injury; and (b) alleged complications not experienced by Mr. Milanesi." MIL No. 4 at 1, ECF No. 176.)

The "defects," "risks," and "complications" to which Defendants refer are (1) the ring breaks and injuries from those breaks that occurred in the Composix Kugel and allegations about polypropylene or the polypropylene mesh degrading in the human body.

1. Ring Breaks

Defendants make the same arguments here that they do in Defendants' MIL No. 1, which this Court dealt with above. They continue to argue that "Plaintiffs should not be allowed to confuse the jury and waste time by delving into these irrelevant and unclaimed theories of defect at trial, which largely hinge on a detour into evidence other devices and a recall. *See* Bard's Motion *in Limine* No. 1." *Id*. at 2. For the same reasons set forth above, the Court disagrees with this assessment of Plaintiffs' claims, and finds the information about the ring breaks in the Composix Kugel relevant and not excludable under Rule 403.

2. Degradation of Polypropylene Mesh

The second argument in Defendants' MIL No. 4, is that the Court should exclude as irrelevant and unfairly prejudicial evidence of the polypropylene or the polypropylene mesh degrading in the human body. Specifically, Defendants state that, "[a]s set out in more detail

elsewhere, [see Bard's Motion *in Limine* No. 23], Plaintiffs' principal allegation about polypropylene is that it allegedly degrades in the human body. However, none of Plaintiffs' allegations about polypropylene or the polypropylene mesh in the Ventralex has been linked to Mr. Milanesi's injuries through competent expert testimony." (Defs' MIL No. 4 at 2, ECF No. 176.) This Court disagrees for the same reasons explained in ruling on Defendants' MIL No. 23 and several EMOs issued in this case.

That is, Defendants here move to exclude the same evidence addressed their MIL No. 23, which this Court ruled on in MIL Order No. 19. (ECF No. 286.) In that decision, the Court concluded that "Plaintiffs have put forth expert testimony and opinions about polypropylene degradation and its relevance to the Milanesi case, which this Court has considered under *Daubert* and Federal Rule of Civil Procedure 702, issuing Evidentiary Motions Orders." (MIL Order No. 19 at 5, ECF No. 286.) Thus, the Court determined that the evidence related to polypropylene degradation was relevant to the *Milanesi* case and not excludable under Rule 403.

Specifically, the Court held that Dr. Krpata's "specific causation opinion is that polypropylene exposure at least in part caused [Mr. Milanesi's] injuries. . . . Dr. Mays's opinion is that all polypropylene degrades and causes injury . . . [and] that polypropylene is not suitable for permanent implantation because it degrades." (MIL No. 19, EMO No. 17.)

Additionally, in EMO No. 20, this Court too found this evidence relevant, stating:

> Dr. El-Ghannam's general polypropylene degradation opinions are relevant to this case. Plaintiffs identify a two-step mechanism of injury in all bellwether cases in this MDL, including this case. First, the polypropylene mesh's "adhesion barrier fails, and polypropylene is exposed to underlying organs to which it attaches." (ECF No. 105 at PageID #9151.) As the Court noted in its *Daubert* opinion addressing Dr. Krpata, the precise two-step mechanism of injury here is that the Ventralex buckles due to contracture, which then exposes bare polypropylene to the viscera. (ECF No. 166 at PageID #13590.) Dr. Krpata, a general and specific causation expert, opines on the first step of this mechanism, explaining that polypropylene mesh and ePTFE contract at different rates, causing buckling, and

> the memory recoil ring lacked sufficient rigidity to prevent the buckling. (*Id*.) He also notes that the exposure of bare polypropylene is widely known to be problematic and can cause adhesions, fistula, and erosion. (*Id*.)
>
> Dr. El-Ghannam picks up where Dr. Krpata leaves off, explaining why bare polypropylene causes such injuries. (ECF No. 219 at PageID #14987–90.)

Moreover, in EMO 23, this Court held that Plaintiffs' biomaterial expert, Dr. Babensee, offered admissible polypropylene degradation opinions that are relevant because they explain why exposure to bare polypropylene is problematic. (ECF No. 273.)

Finally, the probative value of this relevant evidence is not "substantially outweighed by a danger of . . . unfair prejudice, confusing the issues, misleading the jury, undue delay, wasting time, or needlessly presenting cumulative evidence." Fed. R. Evid. 403. Thus, this relevant evidence is not excludable under Rule 403.

For these same reasons, the Court **DENIES** Defendants' MIL No. 4. (ECF No. 176.)

IV.

Based on the foregoing, and for the reasons stated in *Johns* MIL Order No. 14, Case No. 18-cv-1509, ECF No. 503, *Milanesi* MIL Order No. 19 (ECF No. 286), *Milanesi* EMO No. 17 (ECF No. 166), *Milanesi* EMO No. 20 (ECF No. 220), *Milanesi* EMO 23 (ECF No. 273), the Court:

1. **DENIES** Defendants' MIL No. 1 to Exclude Evidence and Argument Concerning Composix Kugel Rings Breaks and Recall (ECF No. 172);

2. **DENIES** Defendants' MIL No. 4 to Exclude Evidence and Argument Concerning Alleged Complications and Defects that Did Not Occur in this Case (ECF No. 176); and

3. **DENIES IN PART** Defendants' MIL No. 5 to Exclude Evidence and Argument Concerning FDA Inspections and Third-Party Audits. (ECF No. 190.) Evidence related to FDA

inspections and third-party audits that may have occurred after Mr. Milanesi's implant will be addressed in a separate MIL Order.

As with all *in limine* decisions, this ruling is subject to modification should the facts or circumstances at trial differ from that which has been presented in the pre-trial motion and memoranda.

IT IS SO ORDERED.

12/13/2021
DATE

s/Edmund A. Sargus, Jr.
EDMUND A. SARGUS, JR.
UNITED STATES DISTRICT JUDGE